REMARKS

IDS

Applicants regret that, for the Information Disclosure Statement filed on 19 June 2001, copies of the cited references were not submitted. A supplemental IDS has been submitted herewith and copies of the cited references are provided.

Enablement rejection: Clarification requested

The Office Action discusses the standards of enablement and undue experimentation under 35 USC 112 on pages 3-4, and the breadth of the present claims and other factors on pages 4-7. However, it is not specifically stated which claims stand rejected. To expedite prosecution, Applicants have assumed that an enablement rejection of claims 21-26 has been made; confirmation by the Examiner (or clarification if this is in error) is requested.

On page 6 of the Office Action, the Examiner refers to "Applicants make and test position"; Applicants are unsure of what this refers to and request clarification.

The Office Action states that for the instant specification to be enabling "it needs to provide direction/guidance regarding an acceptable number of different test compounds that inhibit the interaction of a protein comprising SEQ ID NO:6". However, SEQ ID NO:6 is not recited in the claims and is the amino acid sequence of the mouse membrane bound protein. To expedite prosecution and in view of the recitation of SEQ ID Nos: 1 and 2 in the present claims and the description of the invention by the Examiner (page 5, Office Action) as involving SEQ ID NOs: 1 and 2, Applicants assume the enablement issue is with regard to SEQ ID NO:1 (claim 1; human soluble form of protein) and SEQ ID NO:2 (claim 2; human membrane bound form of protein). Confirmation of this by the Examiner, or clarification if this is in error, is requested.

Rejection under 35 USC 112, first paragraph

Applicants respectfully dispute that the present specification, to be enabling, must provide direction or guidance regarding a number of test compounds that inhibit the interaction of polypeptides of SEQ ID NO:1 or 2 with their B-cell receptors. The Office Action states that "due to the broad scope of the claims, the lack of guidance and

insufficient working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to test all the different types of compounds encompassed by the claimed invention would constitute undue experimentation." (Page 7, underlining added)

While realizing that each patent application is evaluated on its own merits, Applicants refer to issued US Patent 7,153,664 as an example of a patent on screening methods.

The claimed invention is a method of screening compounds to identify whether the compounds decrease binding between the recited polypeptide and its B-cell receptor. The claims do not recite the compounds themselves. Applicants submit that one of ordinary skill in the art, given the disclosure of the present specification, could make and use the claimed screening method.

The Office Action states (page 5) that applicant has not provided any guidance "as to what compounds would be tested in order to decrease the binding". Applicants submit that this is irrelevant, as any suitable compound could be tested in the assay – those skilled in the art could readily identify clearly unsuitable compounds (e.g., insoluble compounds, compounds known to disrupt membranes (e.g. detergents)). The claimed invention is not a method of decreasing binding, but a method of screening compounds for this characteristic.

Regarding the quantity of experimentation necessary, the Office Action states that "while testing for compounds that inhibit proteins from binding their receptors are routine, a method of testing particular compounds that inhibit a specific protein such as a protein comprising the amino acid sequence of SEQ ID NO:1 or 2 is not routine and requires more experimentation." (page 6) In support, the Examiner argues that the prior art does not discuss any test compounds that decrease this binding and there are no examples in the specification that indicate the use of a particular test compound for inhibition or decrease of this binding.

Applicants submit that disclosure in the prior art or specification of compounds tested and shown to inhibit binding is not needed to enable the claimed screening method. What must be enabled is the claimed invention; as binding of the polypeptides to B-cells has been shown, and methods of detecting such binding are known in the art, one of

ordinary skill in the art could readily use the claimed assay to screen a multitude of test compounds. As noted by the Examiner, testing for compounds that inhibit proteins from binding their receptors are routine.

The Office Action further states that "determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue". In the present matter, Applicants submit that any experimentation required is not undue, as it is routine. One might have to screen many compounds using this assay to identify ones that inhibit binding (i.e. perform a large number of experiments), however, given the disclosure in the specification of the polypeptides and cells to use, setting up and obtaining results (whether negative or positive) from the assay would require only the routine skill of testing compounds that inhibit proteins from binding to their receptors. Undue experimentation on the method of the claimed assay is not required to use the assay for screening. The present specification discloses polypeptide sequence required for the claimed assay, examples of cells containing the receptor, and examples of detecting binding (see e.g., Examples 6 and 7 regarding binding of soluble D7 (SEQ ID NO:1)).

Applicants refer to *In re Wands*, 8 USPQ2 1400 (Fed. Cir. 1988), where the issue was whether undue experimentation was required to produce monoclonal antibodies needed as part of the claimed assay. (The Wands situation differs from the present situation where the Examiner argues the specification must disclose examples of test compounds; in Wands, the material at issue was antibodies required for the assay). The Wands court found the specification enabling even though the production and screening of numerous hybridomas was necessary, because those of skill in the art at the time would have been able and prepared to screen many hybridomas, using routine methods, to find appropriate ones. While a quantity of experimentation was involved, the court did not find this undue.

Applicants submit that the presently claimed method of screening is enabled by the specification as filed, and request withdrawal of the present rejection.

Indefiniteness Rejection

Claims 21 and 23-26 stand rejected as indefinite. These claims have been amended to obviate the present rejection, and withdrawal is requested.

Conclusion

The Commissioner is hereby authorized to charge any fees required or credit any overpayment to Deposit Account No. 07-1392.

Respectfully submitted,

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